 

# Participant Information Sheet/Consent Form

**Blood Flow Restriction (BFR) in ACL reconstruction rehabilitation.** **A randomised controlled pilot study looking at the effect of BFR on quadriceps and hamstring strength improvement in the first 6 months following ACL reconstruction surgery.**

**Project Sponsor** Clifford Craig Foundation

**Investigators** Jonathan Mulford, Laurent Willemot, Zach Young, Nathan Pitchford, Andrew Williams, Ambrose Moore, Iain Robertson, Luke Haas

**Part 1 What does my participation involve?**

**1 Introduction**

You are invited to take part in this research project because you are planning to have an anterior cruciate ligament (ACL) reconstruction and will need rehabilitation following the procedure. The research project is testing a new method of rehabilitation called blood flow restriction (BFR). While gaining popularity it is still unknown if this method definitely helps or the most effective amount of blood flow restriction.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the methods and procedures involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don’t understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor.

Participation in this research is voluntary. If you don’t wish to take part, you don’t have to. You will receive the best possible care whether or not you take part, and you can remove yourself from this study at ***any*** time without penalty or consequence to your treatment or rehabilitation needs.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

• Understand what you have read

* Consent to take part in the research project
* Consent to have the tests and treatments that are described
* Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep. The Participant Information and Consent form is 11 pages long in total. Please make sure that you have all the pages.

**2 What is the purpose of this research?**

ACL reconstruction (ACLR) is one of the most frequently performed and most successful sports injury surgical interventions. Despite this, the rehabilitation techniques are still evolving. After surgery the thigh muscles (quadriceps and hamstring muscle groups) universally get weak and lose strength. This is related to the trauma of the initial injury, surgery and decreased activity in the early postoperative period.

Participants engage in quadriceps and hamstring training to restore muscle strength after surgery guided by physiotherapists.

The use of Blood flow restriction Training after surgery may help regain muscle growth and strength at lower loads. This may help people recover quicker. However, BFR during post ACL reconstruction exercise therapy has not been adequately studied.

Blood flow restriction is performed by placing a tourniquet on the leg. The best amount of blood flow restriction is also not known.

In this project all participants will receive traditional well-established post ACL reconstruction rehabilitation. In addition to this, all participants will receive BFR rehabilitation but be randomised to different amounts of restriction (high or low). This project aims to compare the results of the two different levels of blood flow restriction.

We anticipate that the findings of this trial will influence standard postoperative rehabilitation protocols for anterior cruciate repair in future.

The physiotherapists involved have extensive clinical experience in providing rehabilitation post ACLR and have been trained in how to correctly apply BFR tourniquets.

The research has been funded by the Clifford Craig Foundation.

**3 What does participation in this research involve?**

If you agree to participate in the study, we will ask you to do the following:

1. Your surgeon will identify you as a potential candidate for the study. Following this if you are interested in the trial, a trial coordinator will contact you to screen for your suitability for the trial. This will involve answering simple questions about your health and past surgical history. If you meet the inclusion criteria, a Participant Information Sheet will be mailed out to you. During these screening procedures, at any stage, if the researchers identify any reason that would put you at increased risk by being involved in the study, or any reason that would make it inappropriate for you to participate in the study, you will be asked not to continue in the study.

If you agree to participate in the study, you will be asked to provide consent, by signing the consent form.

1. If you are eligible to participate, you will be randomly assigned to “high” or “low” blood flow restriction. The term “randomised” means you will not have a choice regarding which group you are in, and you will have equal chance of receiving the “high” or “low” blood flow restriction.
2. As this is a blinded trial, neither you, the study investigators or the strength testers will know which treatment you are receiving until the study is completed. However, the treating physiotherapists will need to know which treatment to provide to which participant.
3. The trial will go for 36 weeks as the effects of BFR on the progression of muscular strength will take this long to be measured adequately. During the trial you will attend the ‘research centre’ for 4 visits in total - at screening/baseline, 6 weeks, 12 and 36 weeks later. Each study visit will take about 60 minutes. We can provide an attendance certificate signed by the research investigator for each study visit.
4. The following measurements will occur during the study period.
	* A baseline strength test will occur at screening, then remeasured again at 6, 12 and 36 weeks post ACLR.
	* Other outcomes tested at these same intervals post-surgery will include VAS scale for pain, thigh circumference, Tegner Lysholm (a questionnaire designed to give information as to how your knee problems have affected your ability to manage in everyday life), return to competitive sport and reinjury rate.

**4 What do I have to do?**

Your physiotherapist will guide you with your routine rehabilitation program. In addition, there will be specific blood flow restriction sessions throughout your rehabilitation process. These blood flow restriction sessions involve placing a pneumatic cuff high on your thigh and then performing exercises with the cuff on as guided by your physiotherapist. The cuff will be inflated and deflated at different time points throughout the session by your physiotherapist.

How often will the blood flow restriction sessions be?

Phase One – 0-6 weeks

BFR is utilised twice a week for a max of 25 minutes during the first phase.

Phase Two – 6-12 weeks

BFR will include weight training

Phase three – After 12 weeks

BFR is weaned.

**5 Other relevant information about the research project**

A total of 30 participants undergoing ACLR aged 16 to 50 years will be recruited.

1. **Do I have to take part in this research project?**

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with the Clifford Craig Foundation or the University of Tasmania.

1. **What are the alternatives to participation?**

You do not have to take part in this research project to receive treatment. You can see your doctor or health care professional to discuss different treatment options for your ACLR and rehabilitation. Please feel free to discuss these with your healthcare worker before deciding whether or not to take part in this research project. Your study doctor will discuss these options with you before you decide whether or not to take part in this research project.

1. **What are the possible benefits of taking part?**

We cannot guarantee or promise that you will receive any benefits from this research. However, some participants may experience possible benefits, such as an improvement in strength of quadriceps and hamstrings and reduced chance of reinjury. If this study shows that BFR is effective in mitigating muscular atrophy following ACLR, it may enable this treatment to be available to more people in the future. We will inform you of any abnormal findings from strength testing, and other tests, so that you can then consult with your doctor.

1. **What are the possible risks and disadvantages of taking part?**

Medical treatments often cause side effects. You may have none, some or all of the effects listed below, and they may be mild, moderate or severe. If you have any of these side effects, or are worried about them, talk with your study doctor. Your study doctor and physiotherapist will also be looking out for side effects.

BFR exercises can cause side effects such as fainting and dizziness, numbness, pain and discomfort, and delayed onset muscle soreness. Before BFR application, all participants will be assessed for the risks and contraindications to tourniquet use. Precautions include:

* Previous deep vein thrombosis (DVT) or pulmonary embolism (PE).
* Blood disorders or family history of blood disorders that predisposes to DVT (Factor V Leiden, haemochromatosis etc)
* Cardiac disease
* Peripheral vascular disease
* Varicose veins
* <2 weeks post-operative
* Limited exercise experience
* Reports of pain
* Multiple comorbidities (diabetes, HTN, obesity, vascular issues)

The use of BFR is an established safe and well-tolerated method of muscular rehabilitation. The doses of BFR we use in the study are commonly used for such purposes. However, there may be side effects that the researchers do not expect or do not know about and that may be serious. Tell your study doctor immediately about any new or unusual symptoms that you get.

Many side effects are minor (for example pain around the cuff site) and will go away shortly after treatment ends. However, sometimes side effects can be serious, long lasting or permanent. If a severe side effect or reaction occurs, your study doctor may need to stop your treatment. Tell the study doctor if you have any problems. Your study doctor will monitor for and discuss the best way of managing any side effects with you, should they occur.

If you become upset or distressed as a result of your participation in the research, the study doctor will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research project team. This counselling will be provided free of charge.

**10 What will happen to my test results?**

This research project involves the collection, storage, test and analysis of your health information and test results. By signing the consent form you agree to the study investigator using your test results for this project and storing your results for extended related research and any future research. If future funding is secured, we will be able to measure more outcomes. For any future use of your test results, we will seek the approval from the relevant ethics committees.

Your test results will be re-identifiable such that the research team involved can study the data.

Signing the consent form means that you agree to have this testing; it will not be done without your consent.

1. **What if new information arises during this research project?**

Sometimes during the course of a research project, new information becomes available about the treatment being studied. If this happens, your study doctor will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, your study doctor will make arrangements for your regular health care to continue. If you decide to continue in the research project you will be asked to sign an updated consent form.

Also, on receiving new information, your study doctor might consider it to be in your best interests to withdraw you from the research project. If this happens, he/she will explain the reasons and arrange for your regular health care to continue.

1. **Can I have other treatments during this research project?**

You will be receiving a standard ACL rehabilitation guide following your ACL reconstruction. If you are required to have other surgery or medical treatment rough the study period advise your treating surgeon and physiotherapist.

1. **What if I withdraw from this research project?**

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to discuss any health risks or special requirements linked to withdrawing.

If you do withdraw your consent during the research project, the study investigator and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected by the study investigator up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

1. **Could this research project be stopped unexpectedly?**

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as:

* Unacceptable side effects
* The treatment being shown not to be effective
* The treatment being shown to work and not requiring further testing

1. **What happens when the research project ends?**

At the completion of the trial, if you wish to know whether you received “high” or “low” BFR please contact the research personnel for further information.We will send you a follow-up letter to inform you of the findings of the study.

BFR will be provided to you during the trial as part of your normal rehabilitation process with your treating physiotherapist. The cost of physiotherapy will be as per usual practice for the provider you choose. This may depend on your level of cover with your health fund. Your physiotherapy provider will provide you with an expected out of pocket cost. Surgical fees will be discussed with you by each individual surgeon and are independent from the study.

**Part 2 How is the research project being conducted?**

1. **What will happen to information about me?**

By signing the consent form you agree to the study investigator and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential.

The data we collect or use will be individually identifiable or re-identifiable (i.e. coded). All electronic data will be kept in password protected databases, separate from identifying information. Hard copies of data will be kept in locked filing cabinets with restricted key access, at Tamar Valley Orthopaedics. Access to data will be limited to the chief investigators and support staff only. Data transfer will occur so that the final dataset with re-identifiable (i.e. coded) data can be accessed by all the chief investigators of the study. Re-identified test results will be stored securely at Tamar Valley Orthopaedics and will only be accessible by senior researchers. Identifiable information will not be released to anyone outside the research team. Your information will only be disclosed with your permission, except as required by law.

By signing the consent form you consent to the study investigator using your data collected for this project for extended (related research) or unspecified (any future research) use. Please refer to section 10 (page 8) for information about the potential future use of your data.

Test results, information from questionnaires and examinations will be retained for at least 15 years upon completion of the study. This research project does not involve the establishment of a databank.

It is necessary that your local doctor be advised of your decision to participate in this research project. By signing the consent section, you agree to your local doctor being notified of your decision to participate in this research project.

It is anticipated that the results of this research project will be published and presented in a variety of forums. In any publication, report, or presentation, information will be provided in such a way that you cannot be identified, except with your permission. This confidentiality will be maintained by presenting aggregate data. Should any sharing of data be considered (e.g. for combining data with other studies), then data sharing will strictly occur in a re-identified (i.e. coded) manner. In the event where personal information may need to be shared (e.g. data linkage), we will contact you or your guardian for consent for data sharing.

In accordance with relevant Australian and Victorian privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

1. **Injury**

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

1. **Who is organising and funding the research?**

This research project is being conducted in Private Surgical practice of Mr Mulford, Moore, Marshall, Penn, Van Winden and Taylor. Private Physiotherapy practices in Northern Tasmania.

University of Tasmania funded by the Clifford Craig Foundation.

By taking part in this research project, you agree that samples of your test results or knowledge acquired through analysis of your treatment may directly or indirectly benefit the University of Tasmania and the Clifford Craig Foundation financially.

You will not benefit financially from your involvement in this research project even if, for example, your results (or knowledge acquired from analysis of your samples) prove to be of commercial value to the University of Tasmania and the Clifford Craig Foundation.

In addition, if knowledge acquired through this research leads to discoveries that are of commercial value to the University of Tasmania and the Clifford Craig Foundation, the study doctors or their institutions, there will be no financial benefit to you or your family from these discoveries. No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

1. **Who has reviewed the research project?**

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project will be reviewed and approved by the Tasmanian Health & Medical Human Research Ethics Committee.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

1. **Further information and who to contact**

The person you may need to contact will depend on the nature of your query.

If you would like any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), please contact the principal investigators.

Professor Jonathan Mulford: (03) 6388 9250 jonathanmulford1971@gmail.com

If you have any other questions you wish to be answered before consenting or during the course of the study, you can also contact the Clinical Trial Coordinator: ‘Insert Contact here’

If you have medical concerns outside office hours, please contact Orthopaedic Registrar at the Launceston General Hospital.

For matters relating to research at the site at which you are participating, or if you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, you may contact the Executive Officer of the HREC (Tasmania) Network on (03) 6226 7479 or email human.ethics@utas.edu.au. The executive officer is the person nominated to receive complaints from research participants. You will need to quote **Reference # ‘insert reference number’….**

# Consent Form

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| **Title**  | Blood Flow Restriction (BFR) in ACL reconstruction rehabilitation. A randomised controlled pilot study looking at BFR effect on quadriceps and hamstring strength in the first 6 months following ACL reconstruction surgery |
| **Short Title**  | BFR ACL  |
| **Project Number**  | …  |
| **Project Sponsor**  | Clifford Craig Foundation  |
| **Principal Investigators**  | Jonathan Mulford, Laurent Willemot, Zach Young, Nathan Pitchford, Andrew Williams, Ambrose Moore, Iain Robertson, Luke Haas |
| **Location**  | Northern Tasmania  |

## Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to the University of Tasmania concerning my rehabilitation and treatment for the purposes of this project. I understand that such information will remain confidential.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

I understand that, if I decide to discontinue the study treatment, I may be asked to attend follow up visits to allow collection of information regarding my health status.

 Name of participant (please print)

 Signature Date

## Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

 Name of researcher† (please print)

 Signature Date

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.